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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,516	02/06/2002	Gillian Rosemary Bullock	4-30755B	4159

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,516	BULLOCK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 8, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-38* is/are pending in the application.

4a) Of the above claim(s) *15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/468,663.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed August 8, 2006 have been received and entered into the application.

Action Summary

The rejection of claims 8, 9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) of record is hereby expressly with drawn in view of Applicants' amendment of canceling the claims.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25, 26, 37 and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Wagner et al. (WO 97/49394 A2) of record.

Wagner et al. illustrate a formula comprising valsartan (free form) 160mg, microcrystalline cellulose 75.5mg and polyvinylpyrrolidone (CROSPOVIDONE) 9mg tablet obtained by compression (Example 2, page 14, line 16-17). The amounts of above valsartan and microcrystalline cellulose are within Applicants' ratio set forth in claims 25 and 26. The limitation of having a dissolution rate of above 90% over 30 minutes set forth in claim 38 is inherent property of same composition comprising same active agents with same amounts taught by Wagner et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-30, 33, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) of record.

Wagner et al. illustrate a formula comprising valsartan 160mg, microcrystalline cellulose 75.5mg and polyvinylpyrrolidone (CROSPOVIDONE) 9mg tablet obtained by compression (Example 2, page 14, line 16-17). Wagner et al. teach that valsartan is preferably in its free form, that is, not in one of its salt forms. (page 4, line 11). Wagner et al. teach crospovidone is most preferred disintegrant in the dosage form and the

dosage range of crospovidone is preferably present in an amounts of from 10 to 20 %, e.g. about 13% by weight. (page 4, lines 22-23, and page 7, lines 20-23, page 15 Example 2). Wagner et al. teach preferred dosage range of valsartan as 10 to 250mg consists entirely of valsartan, more preferably for example 40, 80 or 160mg, and the effective amounts can be easily determined by person skilled in the art by routine experimentation and with no undue burden. (page 2, lines 15-22). Wagner et al. teach the binder can be employed as an additive and microcrystalline cellulose is preferred in the dosage form. (page 5, first and last paragraph; page 7, 3rd paragraph, last sentence). Wagner et al. teach the amount of binder may vary within a range of from about 10 to 45% by weight. (page 5, last paragraph, 4th sentence).

Wagner does not expressly teach the specific ratio set forth in claims 28 and 29, specified amounts of active agents comprising formulations set forth in claims 30, 33-35.

It would have been obvious to one of ordinary skill in the art to modify the amounts of an illustrated formulation of Wagner and optimize each of the ingredients therein because Wagner teaches the amounts of the agents to be employed that are encompassing and/or overlapping the amounts and ratios claimed by Applicants. It is noted that Wagner teaches the specific amounts of valsartan to be employed are more preferably for example 40, 80 or 160mg as set forth in Applicants' amounts set forth in claims 33-35. It is noted that Wagner teaches the ranges of microcrystalline cellulose can be range from about 10 to 45% which overlaps and encompasses Applicants' amounts set forth in claims 30, 33-35. Wagner further teaches the amounts of

crospovidone to be employed from 10 to 20% encompasses/overlapped Applicants' amounts set forth in the claims. One of ordinary skill in the art would have been motivated to optimize the dosage and ratio of the agent to be employed in the formulation of Wagner within the dosages of each of the agents taught by Wagner well taught to be easily determined by person skilled in the art by routine experimentation and with no undue burden and pharmaceutically acceptable as a compressed tablet taught by Wagner.

Claims 31, 32 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) of record in view of Pool et al. (1998).

Wagner et al. as applied as before.

Wagner et al. do not teach the specific amount (320mg) of valsartan set forth in claims 31, 32 and 36.

Pool et al. teach that the integrated analysis demonstrated a clear increase in blood-pressure-lowering efficacy with increasing dose across the range 10 to 320mg valsartan. The data demonstrate that valsartan provides dose-responsive antihypertensive efficacy across the therapeutic dose range with 10, 20, 40, 80, 160 and 320mg. (abstract).

It would have been obvious to one of ordinary skill in the art to modify the dose of valsartan in Wagner et al.'s formulation to 320mg as taught by Pool et al. because there is clear increase in blood-pressure-lowering efficacy with increasing dose of valsartan as taught by Pool et al. One would have been motivated to increase the dose of

valsartan taught by Wagner et al. to 320mg in order to achieve an increased therapeutic effect of lowering blood pressure with higher dosage taught by Pool et al. There is a reasonable expectation of successfully treating hypertension with higher dosage of valsartan than Wagner's amount because Pool et al. demonstrate that there is clear increase in blood pressure lowering efficacy with increased dose of valsartan. With regard to upper limit of valsartan set forth in claim 31 is obvious within skilled in the art because Wagner teaches the dosage amount of valsartan is easily determined by person skilled in the art by routine experimentation and with no undue burden. One of ordinary skill in the art would have easily determine upper limit or maxium dosage of valsartan to be employed accordance of a patient to be treated based on his medical condition/history.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed August 8, 2006 have been fully considered but they are not persuasive. Applicants argue that while Wagner et al. describe a range for

binders, Wagner clearly teaches in the examples that when the binder is microcrystalline cellulose, the amount of binder required is between less than 30% and specifically 21% and therefore the required amount of microcrystalline cellulose taught by Wagner does not overlap with the amount required by Applicants. This is not persuasive because Wagner illustrates a tablet formulation comprising valsartan, microcrystalline cellulose and crospovidone with their amounts within Applicants ratio set forth in claims 25 and 26. Therefore the amount of microcrystalline cellulose overlaps and it is clearly within Applicants claimed ratio set forth in the claims. It is noted that Wagner's' amount of binders (microcrystalline cellulose) employed extend from about 10 to 45% and clearly this range encompasses/overlaps Applicants' claimed amount of less than 30% microcrystalline cellulose. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sreenivasan Padmanabhan
Supervisory Patent Examiner
Art Unit 1617

Jmk
October 23, 2006

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER